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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,317	07/17/2003	Brian R. Micheli	DI-5829	3439

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EXAMINER

DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,317

Applicant(s)

MICHELI, BRIAN R.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,5,8 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24,25,27 and 28 of copending Application No. 10/624,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1,5,8 and 28 define the same combination of peritoneal dialysis components as claims 24,25,27 and 28, consisting of: catheter, fluid circuit, dialysate supply, cycler pump, cleaning device and discharge path/drain.

For claims 1,5, and 8, the only substantial difference is in recitation of the obvious expedient of the instant claims to operate the cycler pump in a continuous manner, pumps utilized in dialysis or other medical systems obviously can be operated either intermittently or continuously.

With respect to claim 28, the only significant difference is in recitation of amended claim 28 of the closed fluid path being a single path. However, any such closed fluid path, would inherently be expected to constitute a single path, as opposed to plural, more complex interacting paths .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12,15-21,24-26,28,29,32-37,40-45,48-55,57,58,and 61 remain rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al Journal Publication "Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration" from Scholarly Review, ASAIO Journal 1999, pages 372-378. Roberts et al disclose the claimed peritoneal dialysis system including elements of dual lumen catheter (page 372, 1st column, and components shown in figure 3 that include closed loop fluid circuit, plural dialysate supplies, therapy fluid/osmotic agent or 'infusate' supply, cycler pumps, cleaning device at least including a sorbent cartridge and a discharge path/drain in the vicinity of the dialysate supplies. Also shown in figure 3 is a reservoir as required by independent claims 9,32,34,41 and 51. For independent claims 28,and 51, removal of urea is discussed on page 373, 1st column and in Table 1.

Regarding various dependent claims; two separate dialysate supplies totaling less than 4 or 6 liters are shown as well in figure 3, with osmotic agent supply inherently totaling less than 1.5 liters (see discussion on page 373, 2nd column, removal of urea by

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either non-selective sorbent or urease-urea removal specific media (page 374, 2nd column and page 376, 2nd column), presence of sorbent material (page 373, 2nd column), maintaining of high urea and creatinine clearance levels (see Table 1 on page 376), the infusate constituting electrolytes and components with osmotic diffusive enhancing characteristics (page 376, see paragraph entitled "Wearable Regeneration Systems"), treatment periods of 8 hours or less (page 376, 2nd column, 3rd paragraph), continuous circulation and supply portions of 4 liters or less each (page 372, 1st column), and option of lower 3 liter or less amounts of osmotic solution utilized (see especially page 374 concerning treatment of relatively smaller canine systems).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13,14,22,23,31,38,39,46,47,56 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Roberts et al Journal Article in view of Shockley et al patent 5,631,025.

Claims 13,14,22,23,38,39,46,47 and 56 differ in requiring that the osmotic agent fluid supply include dextrose. Shockley et al teach use of dextrose at column 5, lines 18-25 and supporting rationale. It would have been obvious to one of ordinary skill in the art to have included dextrose in the infusate supply of Roberts et al, as taught by Shockley, in order to enhance removal of various toxins by ultrafiltration from the recirculating dialysate.

Claims 31 and 60 differ in requiring substantial microglobulin clearance or removal rates. Schockley also teach removal of microglobulin at column 10, lines 13-18. It would have been further obvious to one of ordinary skill in the art to have employed a cleaning device with capability of removal of substantial amounts of the microglobulin of treated patients with the Roberts et al system, as suggested by Schockley et al, since microglobulin as a well known toxin accumulating in the peritoneal cavity requiring removal.

Applicant's arguments filed on 1/11/2006 with respect to rejections based on the Roberts publication have been fully considered but they are not persuasive. It is argued that the Roberts article does not disclose a closed system since the Instant Specification identifies the dialysate flow path of Roberts as open to the atmosphere. However, it is submitted that the instant claims are reciting a **"closed fluid path" AND NOT a "closed system"**. **The instant Specification at pages 5 and 6 makes it clear that "closed fluid path" refers to a recirculating loop to which some fluids may be added as necessary, and does pose a limitation as to whether any portion of the path lacks sealing so as to be open to the atmosphere.**

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It is additionally submitted that the statement in the Instant Specification as to the Roberts system "being open to the atmosphere" is not supported by the actual text of Roberts; Roberts is silent regarding any portion or component of his system being either open to the atmosphere or sealed and hence closed to the atmosphere.

Applicant's arguments with respect to claims 1,5,8 and 28 with respect to the Double Patenting Rejection have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Claims 27,30,50 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Roberts et al Journal article in view of Ash patent 6,409,699. Claims 27,30,50 and 59 differ in requiring removal of phosphate or maintaining of substantial phosphate clearance rates. Ash teaches in column 15, lines 35-column 16, line 8 that phosphates are a toxin accumulating in the peritoneal cavity and can be removed by ultrafiltration of the dialysate. It would have also been obvious to have employed an ultrafilter in the circuit of Roberts et al to remove phosphates, as taught by Ash, in order to more completely clear the peritoneal cavity of toxin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public

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PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

February 20, 2006


JOSEPH DRODGE
PRIMARY EXAMINER